

§ 558.76

21 CFR Ch. I (4–1–01 Edition)

| Arsanilic acid in grams per ton | Combination in grams per ton | Indications for use | Limitations | Sponsor |
|---------------------------------|------------------------------|---|---|---------|
| (ii) 90 (0.01%) | | 1. Chickens; growth promotion and feed efficiency; improving pigmentation.. |do | 015565 |
| | | 2. Turkeys; growth promotion and feed efficiency; improving pigmentation. |do | 015565 |
| | | 3. Swine; and aid in control of swine dysentery (hemorrhagic enteritis, bloody dysentery). |do | 015565 |
| (iii) | Erythromycin 4.6 | Chickens; growth promotion and feed efficiency; improving pigmentation.. | As erythromycin thiocyanate; withdraw 5 days before slaughter; as sole source of organic arsenic.. | 012487 |
| (iv) | Erythromycin 4.6 to 18.5. | Chickens; growth promotion and feed efficiency; improving pigmentation. | As erythromycin thiocyanate; withdraw 5 days before slaughter; as sole source of organic arsenic. | 15565 |
| (v) | Erythromycin 9.25 ... | Chickens; growth promotion and feed efficiency; improving pigmentation.. | As erythromycin thiocyanate; withdraw 5 days before slaughter; as sole source of organic arsenic.. | 012487 |
| (vi) | Erythromycin 92.5 ... | 1. Chickens; as an aid in the prevention of chronic respiratory disease during periods of stress; growth promotion and feed efficiency; improving pigmentation. | As erythromycin thiocyanate; feed for 2 days before stress and 3 to 6 days after stress; withdraw 5 days before slaughter; as sole source of organic arsenic. | 015565 |
| | | 2. Chickens; as an aid in the prevention of infectious coryza; growth promotion and feed efficiency; improving pigmentation. | As erythromycin thiocyanate; feed for 7 to 14 days; withdraw 5 days before slaughter; as sole source of organic arsenic. | 015565 |
| (vii) | Erythromycin 185 | Chickens; as an aid in the prevention and reduction of lesions and in lowering severity of chronic respiratory disease; growth promotion and feed efficiency; improving pigmentation. | As erythromycin thiocyanate; feed for 5 to 8 days; do not use in birds producing eggs for food purposes; withdraw 5 days before slaughter; as sole source of organic arsenic. | 15565 |

(2) Arsanilic acid may be used in accordance with the provisions of this section in the combinations provided as follows:

(i) Amprolium in accordance with § 558.55.

(ii) Amprolium and ethopabate in accordance with § 558.58.

(iii) Bacitracin zinc in accordance with § 558.78.

(iv) Bacitracin and zoalene in accordance with § 558.680.

(v) Zoalene in accordance with § 558.680.

[41 FR 10992, Mar. 15, 1976, as amended at 42 FR 18617, Apr. 8, 1977; 51 FR 7395, Mar. 3, 1986; 51 FR 33897, Sept. 24, 1986; 54 FR 18281, Apr. 28, 1989; 56 FR 19268, Apr. 26, 1991; 60 FR 39847, Aug. 4, 1995; 66 FR 14074, Mar. 9, 2001]

§ 558.76 Bacitracin methylene disalicylate.

(a) *Approvals.* Type A medicated articles: 10, 25, 30, 40, 50, 60, or 75 grams per pound to 046573 in § 510.600(c) of this chapter.

(b) *Special considerations.* The quantities of antibiotics are expressed in terms of the equivalent amount of antibiotic standard.

(c) *Related tolerances.* See § 556.70 of this chapter.

(d) *Conditions of use.* (1) It is used as follows:

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| Bacitracin methylene disalicylate in grams per ton | Combination in grams per ton | Indications for use | Limitations | Sponsor |
|--|---|---|---|-------------------|
| (i) 4 to 50 | | Chickens, turkeys, and pheasants; increased rate of weight gain and improved feed efficiency ¹ . | | 046573 |
| (ii) 5 to 20 | | Quail not over 5 weeks of age; increased rate of weight gain and improved feed efficiency ¹ . | | 046573 |
| (iii) 10 to 25 | | Chickens; for increased egg production and improved feed efficiency for egg production. | For first 7 months of production | 046573 |
| (iv) 10 to 30 | | Swine: for increased rate of weight gain and improved feed efficiency. | For growing and finishing swine | 000004 and 046573 |
| | Chlortetracycline approximately 400, varying with body weight and food consumption to provide 10 milligrams per pound of body weight per day. | Swine; for increased rate of weight gain and improved feed efficiency; for treatment of bacterial enteritis caused by <i>Escherichia coli</i> and <i>Salmonella choleraesuis</i> and bacterial pneumonia caused by <i>Pasteurella multocida</i> susceptible to chlortetracycline. | Feed for not more than 14 days to provide 10 milligrams of chlortetracycline per pound of body weight per day; as chlortetracycline provided by Nos. 000004 and 046573 in § 510.600(c) of this chapter. Type C feed may be prepared from Type B feed containing 1 to 3 grams per pound BMD with 400 grams per pound CTC, to 046573 in § 510.600(c). | 000004 and 046573 |
| | | Swine; for control of porcine proliferative enteropathies (ileitis) caused by <i>Lawsonia intracellularis</i> susceptible to chlortetracycline.. | Feed for not more than 14 days; chlortetracycline and BMD® as provided by 046573 in § 510.600(c) of this chapter. | 046573 |
| (v) [Reserved] | | | | |
| (vi) 50 | | Broiler chickens; as an aid in the prevention of necrotic enteritis caused or complicated by <i>Clostridium</i> spp. or other organisms susceptible to bacitracin. | | 046573 |
| | | Replacement chickens; as an aid in the prevention of necrotic enteritis caused or complicated by <i>Clostridium</i> spp. or other organisms susceptible to bacitracin | Feed continuously as sole ration | 046573 |
| (vii)—(viii) [Reserved] | | | | |
| (ix) 100 to 200 | | Broiler chickens; as an aid in the control of necrotic enteritis caused or complicated by <i>Clostridium</i> spp. or other organisms susceptible to bacitracin. | | 046573 |
| | | Replacement chickens; as an aid in the control of necrotic enteritis caused or complicated by <i>Clostridium</i> spp. or other organisms susceptible to bacitracin | Feed continuously as sole ration. Start at first clinical signs of disease, vary dosage based on severity of infection, administer continuously for 5 to 7 days or as long as clinical signs persist, then reduce medication to prevention level (50 g/t). | 046573 |
| (x) 200 | | Turkeys; as an aid in the control of transmissible enteritis in growing turkeys complicated by organisms susceptible to bacitracin methylene disalicylate. | | 046573 |
| | | Quail; for the prevention of ulcerative enteritis in growing quail due to <i>Clostridium colinum</i> susceptible to bacitracin methylene disalicylate | From Type A medicated articles containing 25, 40, or 50 grams of bacitracin methylene disalicylate. Feed continuously as the sole ration. | 046573 |

| Bacitracin methylene disalicylate in grams per ton | Combination in grams per ton | Indications for use | Limitations | Sponsor |
|--|------------------------------|---|---|---------|
| (xi) 250 | | 1. Growing/Finishing Swine: For control of swine dysentery associated with <i>Treponema hyodysenteriae</i> on premises with a history of swine dysentery but where signs of the disease have not yet occurred; or following an approved treatment of the disease condition. | As the sole ration. Not for use in swine weighing more than 250 pounds. Diagnosis should be confirmed by a veterinarian when results are not satisfactory. | 046573 |
| | | 2. Pregnant sows: For control of clostridial enteritis caused by <i>C. perfringens</i> in suckling piglets.. | As the sole ration. Feed to sows from 14 days before through 21 days after farrowing on premises with a history of clostridial scours. Diagnosis should be confirmed by a veterinarian when results are not satisfactory. | |

¹ These conditions are NAS/NRC reviewed and found effective. Applications for these uses may not require effectiveness data as specified by § 514.111 of this chapter, but may require bioequivalency and safety information.

(2) It is used as bacitracin methylene disalicylate in feed for animals as follows:

(i) *Amount.* 70 milligrams per head per day.

(a) *Indications for use.* Feedlot beef cattle; reduction in the number of liver condemnations due to abscesses.

(b) *Limitations.* Administer continuously throughout the feeding period.

(ii) *Amount.* 250 milligrams per head per day.

(a) *Indications for use.* Feedlot beef cattle; reduction in the number of liver condemnations due to abscesses.

(b) *Limitations.* Administer continuously for 5 days then discontinue for subsequent 25 days, repeat the pattern during the feeding period.

(3) Bacitracin methylene disalicylate may also be used with:

(i) Amprolium as in § 558.55.

(ii) Amprolium and ethopabate as in § 558.58.

(iii) Carbarsone (not USP) as in § 558.120.

(iv) Decoquinatone alone and with roxarsone as in § 558.195.

(v) Fenbendazole as in § 558.258.

(vi) Halofuginone hydrobromide alone and with roxarsone as in § 558.265.

(vii) Hygromycin B as in § 588.274.

(viii) Ivermectin as in § 558.300.

(ix) Lasalocid sodium alone and with roxarsone as in § 558.311.

(x) Monensin alone and with roxarsone as in § 588.355.

(xi) Narasin alone and with roxarsone as in § 558.363.

(xii) Nicarbazine alone and with narasin and roxarsone as in § 558.366.

(xiii) Nitarsone as in § 558.369.

(xiv) Robenidine alone and with roxarsone as in § 558.515.

(xv) Salinomycin alone and with roxarsone as in § 558.550.

(xvi) Semduramicin alone and with roxarsone as in § 558.555.

(xvii) Zoalene alone and with arsanilic acid as in § 558.680.

[41 FR 10993, Mar. 15, 1976]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 558.76, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and on GPO Access.

§ 558.78 Bacitracin zinc.

(a) *Approvals.* To sponsors listed in § 510.600(c) of this chapter for use as in paragraph (d) of this section as follows:

(1) To 046573: 50 grams per pound as in paragraphs (d)(1)(i), (d)(1)(ii), (d)(1)(iii), (d)(1)(iv), and (d)(2) of this section.

(2) To 063238: 10, 25, 40, and 50 grams per pound as in paragraphs (d)(1)(i), (d)(1)(ii), (d)(1)(v), (d)(1)(vi), (d)(2), and (d)(3) of this section.

(3) To 000010: 5 and 50 grams per pound for chickens as in paragraph (d)(1)(i) of this section.

(b) *Special considerations.* The quantities of antibiotics are expressed in terms of the equivalent amount of antibiotic standard.